UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/588,077	05/01/2007	Meir Uri	27575U	4031

20529 7590 04/01/2010

THE NATH LAW GROUP
112 South West Street
Alexandria, VA 22314

EXAMINER	
KOAGEL, JONATHAN BRYAN	
ART UNIT	PAPER NUMBER
3744	
MAIL DATE	DELIVERY MODE
04/01/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/588,077	URI ET AL.	
	Examiner	Art Unit	
	JONATHAN KOAGEL	3744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 December 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26 and 44-47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-26 and 44-47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

Claim 4 is objected to because of the following informalities: The recitation "surfaces of the plates are parallel to side walls of the containers (line 2) should be changed to --surfaces of the plates are parallel to side walls of the container-- for clarity and proper antecedent basis. Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-26, 44, 45 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Arav US Patent No. 5,873,254 and Polk US Patent No. 3,074,247.

Regarding claim 1, Arav teaches in fig. 1a, an apparatus capable of freezing a biological sample in a flexible container 38, the apparatus comprising, a cooling axis (horizontal axis that runs through 12, 14 and 16), at least one set of two cooling plates 12, 14 with inner surfaces (dashed lines of 12 and 14) positioned along the cooling axis, each at least one set of two cooling plates comprising a first longitudinal plate dimension (vertical dimension of plates 12 and 14) perpendicular to the cooling axis, and a second horizontal plate dimension (horizontal dimension of plates 12, 14) parallel to the cooling axis, a passage 36 defined between the inner surfaces of the plates 12,

14, the passage 36 comprising a height no larger than the first longitudinal plate dimension, a motion unit 44 capable of moving the container 38 through the passage 36 along the cooling axis such that the sample is cooled. Straw 38 is considered a flexible container because a person of ordinary skill in the art would have known at the time of invention that a straw is flexible. Furthermore, with enough pressure or force applied to the straw, the straw can be deformed, deeming it a flexible container. Arav fails to explicitly teach the passage having an inner width that conforms to an outer width of the container and moving the container through the passage such that the sample is cooled by conduction from direct contact between the container and the inner surfaces of the plates.

However, Polk teaches in figs. 3 and 6, a passage 16 between inner surfaces of cooling plates 11 comprising an inner width that conforms to an outer width of the container P and moving the container through the passage 16 (via elevator 15) along a cooling axis such that the package is cooled by conduction from direct contact between the container and the inner surfaces of the plates 11. It would have been obvious to a person of ordinary skill in the art to allow for the passage inner width to conform to a container outer width in order to increase the heat transfer rate from the cryogenic fluid to the sample container to achieve an efficient and fast method of freezing a biological sample.

It would have been obvious to a person of ordinary skill in the art at the time of invention to modify Arav with the teachings of Polk to include an inner width that conforms to an outer width of the container and cooling along the cooling axis by

conduction between the inner surfaces of the cooling plates and the container that when combined with Arav, cooling of the sample would be accomplished by conduction from direct contact between the container and the inner surfaces of the plates in order to increase the amount of heat transferred from the container to the cryogenic fluid. This results in a faster cooling rate due to the direct contact of the sample container and the plate containing the cryogenic fluid.

Regarding claim 2, Arav as modified above teaches the invention as disclosed and Arav further teaches in fig. 1a, wherein the plates 12, 14 are oriented vertically.

Regarding claim 3, Arav as modified above teaches the invention as disclosed and Polk further teaches in fig. 1, wherein a set of plates 11 are oriented horizontally (when fig. 1 is viewed from an orientation of having an upper and a lower plate).

Regarding claim 4, Arav as modified above teaches the invention as disclosed and Polk further teaches in fig. 5, wherein the inner surfaces of the plates 11 are parallel to side walls of the container P.

Regarding claim 5, Arav as modified above teaches the invention as disclosed and Polk further teaches in fig. 5, a retention device 15 capable of holding the container P.

Regarding claim 6, Arav as modified above teaches the invention as disclosed and further teaches in fig. 1, the at least one set of cooling plates 12, 14 separated by a gap 18. Polk teaches in fig. 1, an additional set of cooling plates 11. It would have been obvious to a person of ordinary skill in the art at the time of invention to include an additional set of cooling plates so that two or more sets of cooling plates would be arranged along the cooling axis adjacent to each other wherein the sets of cooling plates are separated by a gap in order to allow for a longer passageway which results in a longer cooling process for samples that need long term storage cooling. The gap allows the user to see into the passageway to prevent a sample from becoming too frozen.

Regarding claim 7, Arav as modified above teaches the invention as disclosed and Arav further teaches in fig. 1B, wherein the cooling plates comprise at least one channel 72, 54 capable for flow of a cryogenic fluid therethrough (column 4 lines 55-62).

Regarding claim 8, Arav as modified above teaches the invention as disclosed and Arav further teaches wherein the cryogenic fluid comprises liquid nitrogen (column 4 lines 55-62).

Regarding claim 9, Arav as modified above teaches the invention as disclosed and Arav further teaches feedback control system (not shown column 4 lines 22-25) capable of controlling at least one freezing parameter.

Regarding claim 10, Arav as modified above teaches the invention as disclosed and Arav further teaches in fig. 1a, a heating arrangement 56, 57, 58 associated with the cooling plates (column 4 lines 9-13).

Regarding claim 11, Arav as modified above teaches the invention as disclosed and Arav further teaches wherein the heating arrangement 56, 57, 58 comprises at least one electric resistance heater (column 4 lines 9-13).

Regarding claim 12, Arav as modified above teaches the invention as disclosed and Arav further teaches wherein the feedback control system comprises temperature sensors (column 4 lines 22-25).

Regarding claim 13, Arav as modified above teaches the invention as disclosed and Arav further teaches wherein the feedback control system comprises a processor. Arav discloses thermocouples which need to send information sensed to a controller or processor and therefore it is obvious that Arav has a processor.

Regarding claim 14, Arav as modified above teaches the invention as disclosed and Arav further teaches in fig. 1B, wherein the processor is capable of controlling at least one of, flow of cryogenic fluid (column 4 lines 53-62). Arav disclosed an electrically activated valve which has to be controlled by a controller or processor to control the flow of cryogenic fluid.

Regarding claim 15, Arav as modified above teaches the invention as disclosed and Arav further teaches in fig. 1a, a monitoring means 60, 64 (column 4 lines 41-45).

Regarding claim 16, Arav as modified above teaches the invention as disclosed and Arav further teaches wherein the monitoring means 60, 64 comprises a video camera (column 4 lines 41-45).

Regarding claim 17, Arav as modified above teaches the invention as disclosed and Arav further teaches in fig. 1, wherein the monitoring means comprises a device 64 capable of taking a temperature measurement of the biological sample during freezing (column 4 lines 49-51).

Regarding claim 18, Arav as modified above teaches the invention as disclosed and Arav further teaches wherein the device 64 is an infrared thermograph (column 4 lines 49-51).

Regarding claim 19, Arav as modified above teaches the invention as disclosed and Arav further teaches in fig. 1, a first chamber (passage in 12) capable of receiving the container, a second chamber (passage in 14) capable of performing freezing and a third chamber (passage in 16) capable of removal of the container 38 after freezing, the chambers constituting at least a portion of the passage 36.

Regarding claim 20, Arav as modified above teaches the invention as disclosed and Arav further teaches in fig. 1a, wherein the apparatus is capable of initiating freezing within the first chamber (passage in 12).

Regarding claim 21, Arav as modified above teaches the invention as disclosed and Arav further teaches in fig. 1a, wherein the apparatus is capable of initiating freezing external to the passage 36. Refrigeration device 50 is capable of initiating the freezing before (left of) the passage 36 through convection within the passage.

Regarding claim 22, Arav as modified above teaches the invention as disclosed and further teaches in fig. 1a, wherein the apparatus is capable of initiating freezing in an area of the container 38 (before entering passage 36, via refrigeration device 50), and to introduce the container 38 into the passage 36 after the initiation, wherein during the initiation, the container 38 is disposed such that the area is near the top thereof and during introduction into the passage the area is near the front in the direction of movement. Heat will be transferred from the refrigeration device 50 to the top of the container in the initiation phase from convection. When the container enters into the passage 36, the front will be directly contacted with a cold temperature from the refrigeration device 50.

Regarding claim 23, Arav as modified above teaches the invention as disclosed and Arav further teaches in fig. 1, wherein the third chamber (passage of 16) is capable of cooling the container 38 to a temperature which is below that achieved as a result of freezing. The channel 54 near the third chamber (passage of 16) which contains liquid nitrogen (column 4 lines 53-62) can allow heat to be transferred from the frozen container 38 to the liquid nitrogen even after freezing has been achieved.

Regarding claim 24, Arav as modified above teaches the invention as disclosed and Polk further teaches in figs. 1 and 3, wherein the cooling axis (vertical axis in space 16) is disposed vertically.

Regarding claim 25, Arav as modified above teaches the invention as disclosed and Arav further teaches in fig. 1a, the apparatus capable of initiating the freezing internal to the passage 36 (through refrigeration device 50), and capable of moving the container from a lower portion of the passage to a higher portion of the passage. The movement is taking place from a lower portion (left side) of the passage 36 to a higher portion (right side) of passage 36.

Regarding claim 26, Arav as modified above teaches the invention as disclosed and Arav further teaches in fig. 1a, a method of cooling a biological sample, the method comprising providing the apparatus according to claim 1, inserting a container 38 containing a biological sample into the apparatus, providing a predetermined

temperature gradient along the cooling axis and moving the container 38 through the passage 36 along the axis (column 4 lines 1-8, 18-22).

Regarding claim 44, Arav as modified above teaches the invention as disclosed and Arav further teaches in fig. 1a, when the container 38 is in the apparatus, the biological sample (inside of 38) is disposed in the container 38 such that the biological sample remains below the height of the passage. When Arav is modified by Polk, the size of the container will be slightly smaller than the size of the passage. Therefore, the sample will be disposed such that the sample will remain below (or less than) the height of the passage 38.

Regarding claim 45, Arav as modified above teaches the invention as disclosed but fails to explicitly teach the biological sample comprises red blood cells. "Expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim." *Ex parte Thibault,* 164 USPQ 666, 667, (Bd. App. 1969). Furthermore, "[i]nclusion of material or article worked upon by a structure being claimed does not impart patentability to the claims". *In re Young,* 75 F.2d *>996<, 25 USPQ 69 (CCPA 1935) (as restated in *In re Otto,* 312 F.2d 937, 136 USPQ 458, 459 (CCPA 1963)).

Regarding claim 47, Arav as modified above teaches the invention as disclosed and Arav further teaches in fig. 1a, the container 38 appears to have a length that is

much larger than the width of the container. The size of the container having a length that is twenty times larger than the width of the container is recognized as a result effective variable, i.e. a variable which achieves a recognized result. In this case, the length being twenty times larger than the width of the container would allow the container to hold more biological material to be cooled. The larger container size also allows larger samples to be frozen and preserved. This size gives a user more flexibility, as more material can be frozen at one time as well as allowing the cooling apparatus to be capable of freezing and preserving many different sized samples.

Claim 46 is rejected under 35 U.S.C. 103(a) as being unpatentable over Arav and Polk as applied to claim 1 above, and further in view of Eck et al. DE Publication No. 10056181 C1.

Regarding claim 46, Arav as modified above teaches the invention as disclosed but fails to explicitly teach the container is a blood bag.

Eck teaches in fig. 1, the cryogenic storage of blood samples that uses a blood bag 20 to carry the blood (abstract translation lines 1-4). The use of a blood bag allows for a larger storage volume of the biological material to be cooled, allowing more material to be cooled at one time.

It would have been obvious to a person of ordinary skill in the art at the time of invention to modify the combined teachings of Arav and Polk with the teachings of Eck to include a blood bag for the container in order to increase the amount of biological material that can be cooled and stored at one time. The increased size of the bag

allows more material to fit within it. Further, the efficiency of the system is increased as the time needed to freeze a given amount of biological sample is decreased due to the increased capacity when using the blood bag.

Response to Arguments

Applicant's arguments filed 12/8/09 have been fully considered but they are not persuasive.

In response to the applicant's argument regarding a prima facie case of obviousness not being established, the examiner disagrees. The examiner stated in the office action that it would have been obvious to a person of ordinary skill in the art at the time of invention to modify Arav with the teachings of Polk in order to increase the amount of heat transferred from the container to the cryogenic fluid. This results in a faster cooling rate due to the direct contact of the sample container and the plate containing the cryogenic fluid. The combination of Arav and Polk teach all of the limitations as recited in claim 1.

In response to the applicant's argument regarding the straw of Arav and the straw not suitable for large sample and are not flexible, the examiner respectfully disagrees. Straw 38 is considered a flexible container because a person of ordinary skill in the art would have known at the time of invention that a straw is flexible. Furthermore, with enough pressure or force applied to the straw, the straw can be deformed, deeming it a flexible container. The claims do not recite where the container needs to be suitable for large samples. Furthermore, large is a relative term and there

is no indication of the actual size of a large sample. Lastly, Arav teaches the advantage of using thermal gradients to cool the biological sample. Arav does not disclose that the straws cannot be in direct contact with any of the inner surfaces of the blocks. When Polk is combined with Arav and the sample is being cooled by conduction, the thermal gradients will still exist within the system as well as the directional freezing which allows for controlled nucleation according to Arav.

In response to the applicant's piecemeal analysis of the references, it has been held that one cannot show non-obviousness by attacking references individually where, as here, the rejection is based on combinations of references. *In re Keller, 208* USPQ 871 (CCPA 1981).

In response to the applicant's argument regarding the combination of Arav and Polk and the principle mode of operation of Arav would be destroyed, the examiner respectfully disagrees. Arav utilizes directional freezing and implements temperature gradients within cooling plates to allow for controlled nucleation. The introduction of freezing using conduction will not destroy the operation of Arav, as temperature gradients will still occur within the cooling plates so that directional freezing and controlled nucleation can occur.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JONATHAN KOAGEL whose telephone number is (571)270-7396. The examiner can normally be reached on Monday through Friday 7:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cheryl Tyler can be reached on (571)272-4834 or Frantz Jules (571)272-6681. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. K./
Examiner, Art Unit 3744
17 March 2010

/Cheryl J. Tyler/
Supervisory Patent Examiner, Art Unit 3744